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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,333	04/18/2006	Chad E. Bouton	CT/03-012.PCT.US	7092

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EXAMINER	
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3777	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,333	BOUTON ET AL.	
	Examiner	Art Unit	
	Jason Ip	3777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,11-14 and 18-48* is/are pending in the application.

4a) Of the above claim(s) *26-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11-14,18-25,and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 48 is objected to because of the following informalities: The word "shied" in line 1 is a misspelling. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 6-8, 11-14, 18, 19, 24, 25, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carr et al (US Patent No. 5,334,141) in view of Hirschman (US Patent No. 6,408,204 B1), and further in view of Culver et al (US Patent No. 6,487,428 B1).

Regarding claim 1, Carr et al disclose a sensor device comprising a microwave antenna element used to detect a change in the level of fluid within tissue of a body (col. 3, lines 30-52), but do not specifically disclose the sensor device comprising a housing having a plurality of bridge segments, the bridge segments connecting at intersections and being arranged to circumscribe an opening defined by the housing and a plurality of elements at least partially seated within the housing at intersections of the bridge segments, each of the plurality of elements comprising a generally plane mounted to a substrate material at a base of the plane, an outer surface of the plane facing away from the substrate, each of the plurality of elements further comprising an electrical shield surrounding the substrate, or at least a first element pair and a second element pair, the first element pair comprising a first transmitting element and a first receiving element, the second element pair comprising a second transmitting element and a second receiving element. However, Hirschman teaches a sensor device comprising a housing having a plurality of bridge segments, the bridge segments connecting at intersections and being arranged to circumscribe an opening defined by the housing (col. 7, lines 49-52; see Fig. 4), and a plurality of elements at least partially seated within the housing at intersections of the bridge segments, each of the plurality of elements comprising a generally plane mounted to a substrate material at a base of the plane, an outer surface of the plane facing away from the substrate (col. 7, lines 49-67…col. 8, lines 1-4), each of the plurality of elements further comprising an electrical shield surrounding the substrate (col. 6, lines 39-43; col. 7, lines 62-65), and a plurality of elements comprising at least a first element pair and a second element pair, the first element pair comprising a first transmitting element and a first receiving element, the second element pair comprising a second transmitting element and a second receiving element (col. 2, lines 66-

67…col. 3, lines 1-18). Neither Carr et al nor Hirschman specifically disclose that the first antenna element pair and the second antenna element pair are spaced from each other to create an area of reduced sensitivity between the first antenna element pair and the second antenna element pair. However, Culver et al teach a source and detector setup where a gradient of sensitivity is defined by boundary contours (col. 7, lines 40-51). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to apply the teachings of Hirschman to Carr et al, as to provide a well-adapted structure through which to apply extravasation detection, and Culver et al to Carr et al and Hirschman, as to provide differential sensitivity of detection for different geometries of tissue.

Regarding claims 6 and 24, Carr et al disclose an attachment mechanism to operably attach the sensor device to the tissue of the body, the attachment mechanism comprising an adhesive portion defining a cutout region generally coextensive with the opening of the housing, the adhesive portion having one side thereof coated with a first adhesive adapted to removably attach to the tissue and an opposite side thereof coated with a second adhesive adapted to attach to a bottom surface of the housing (col. 4, lines 49-58).

Regarding claims 7 and 25, Carr et al disclose the attachment mechanism further comprising a release band affixed to a perimeter of the adhesive portion (col. 4, lines 49-58).

Regarding claim 8, Carr et al disclose the first adhesive providing less adhesion than the second adhesive (col. 4, lines 49-58).

Regarding claims 11 and 18, Carr et al disclose antenna elements (col. 3, lines 30-52) and Hirschman discloses the application of RF electrical energy to such elements (col. 7, lines 49-55), but neither Carr et al nor Hirschman specifically disclose that the space between the first

element pair and the second element pair being set so that the sensor is insensitive to fluid changes of a predetermined volume within the area of reduced sensitivity. However, Culver et al teach detecting extravasation by checking if a prescribed threshold volume is crossed, at which an injection should be stopped (col. 13, lines 11-14). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to apply the teaching of Culver et al to Carr et al and Hirschman, as to provide a measure of the sensor's sensitivity to detecting volume changes.

Regarding claims 12 and 19, Carr et al disclose antenna elements (col. 3, lines 30-52) and Hirschman discloses the application of RF electrical energy to such elements (col. 7, lines 49-55), but neither Carr et al nor Hirschman specifically disclose a first area of higher sensitivity being defined by the area between the first transmitting element and the first receiving element and a second area of higher sensitivity is defined by the area between the second transmitting element and the second receiving element. However, Culver et al teach a source and detector setup where a gradient of sensitivity defined by boundary contours (col. 7, lines 40-51) and that multiple sources can be paired with multiple detectors (col. 13, lines 15-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to apply the teaching of Culver et al to Carr et al and Hirschman, as to provide differential sensitivity of detection for different geometries of tissue using more than one source/detector pair.

Regarding claim 13, Carr et al disclose a microwave antenna element sensor device used to detect a change in the level of fluid within tissue of a body (col. 3, lines 30-52), but do not specifically disclose one comprising a first element pair comprising a first transmitting element and a first receiving element, the first transmitting element being spaced from and connected to

the first receiving element by a first bridging segment, at least a second element pair comprising a second transmitting element and a second receiving element, the second transmitting element being spaced from and connected to the second receiving element by a second bridging segment, the first element pair and the second element pair being placed in spaced connection by a first spacing segment and a second spacing segment so that an open area is defined by the first element pair, the second element pair, the first spacing segment and the second spacing segment, or a first spacing segment connecting the housing section of the first transmitting element to the housing section of the second transmitting element and a second spacing segment connecting the housing section of the first receiving element to the housing section of the second receiving element. However, Hirschman teaches a sensor comprising a first element pair comprising a first transmitting element and a first receiving element, the first transmitting element being spaced from and connected to the first receiving element by a first bridging segment; and at least a second element pair comprising a second transmitting element and a second receiving element, the second transmitting element being spaced from and connected to the second receiving element by a second bridging segment, the first element pair and the second element pair being placed in spaced connection by a first spacing segment and a second spacing segment so that an open area is defined by the first element pair, the second element pair, the first spacing segment and the second spacing segment, and a first spacing segment connecting the housing section of the first transmitting element to the housing section of the second transmitting element and a second spacing segment connecting the housing section of the first receiving element to the housing section of the second receiving element (col. 7, lines 49-67…col. 8, lines 1-4; see Fig. 4). Neither Carr et al nor Hirschman specifically disclose that the element pairs are spaced from

each other to create an area of reduced sensitivity between the first antenna element pair and the second antenna element pair. However, Culver et al teach a source and detector setup where a gradient of sensitivity defined by boundary contours (col. 7, lines 40-51). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to apply the teachings of Hirschman to Carr et al, as to provide a well-adapted structure through which to apply extravasation detection, and Culver et al to Carr et al and Hirschman, as to provide differential sensitivity of detection for different geometries of tissue.

Regarding claim 14, Carr et al disclose a microwave antenna element sensor device used to detect a change in the level of fluid within tissue of a body (col. 3, lines 30-52), but do not specifically disclose that each antenna element is surrounded by a housing section, each of the elements comprising a substrate mounted within the housing section and a generally planar element mounted to the substrate. However, Hirschman teaches that each element is surrounded by a housing section, each of the elements comprising a substrate mounted within the housing section and a generally planar element mounted to the substrate (col. 7, lines 49-57; see Fig. 4). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to apply the teachings of Hirschman to Carr et al, as to provide a well-adapted structure through which to apply extravasation detection.

Regarding claim 48, Carr et al do not specifically disclose that the electrical shield comprises a rearward section adjacent a rearward side of the substrate, side shields, encompassing sides of the substrate and a forward section adjacent a forward side of the substrate and extending inward from the side shields, a margin being maintained between the planar antenna and the forward section. However, Hirschman teaches a sensor device

comprising a housing having a plurality of bridge segments, the bridge segments connecting at intersections and being arranged to circumscribe an opening defined by the housing (col. 7, lines 49-52; see Fig. 4), and a plurality of elements at least partially seated within the housing at intersections of the bridge segments, each of the plurality of elements comprising a generally plane mounted to a substrate material at a base of the plane, an outer surface of the plane facing away from the substrate (col. 7, lines 49-67…col. 8, lines 1-4), each of the plurality of elements further comprising an electrical shield surrounding the substrate (col. 6, lines 39-43; col. 7, lines 62-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to apply the teachings of Hirschman to Carr et al, as to provide a well-adapted and electrically-shielded structure through which to apply extravasation detection.

5. Claims 2-5 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carr et al (US Patent No. 5,334,141) in view of Hirschman (US Patent No. 6,408,204 B1), and further in view of Culver et al (US Patent No. 6,487,428 B1), as applied to claims 1 and 13 above, and further in view of Cudahy et al (US Patent No. 5,184,620).

Regarding claims 2 and 20, Carr et al disclose antenna elements (col. 3, lines 30-52) and Hirschman discloses the application of RF electrical energy to such elements (col. 7, lines 49-55), but neither Carr et al, Hirschman, nor Culver et al specifically disclose that the RF energy is applied through a cable assembly. However, Cudahy et al teach a cable having a mating terminal electrically connected to electrodes (col. 6, lines 22-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to apply the teaching of Cudahy et al to

Carr et al, Hirschman, and Culver et al, as to provide a means of delivering RF electrical energy to antenna elements.

Regarding claims 3 and 21, neither Carr et al, Hirschman, nor Culver et al specifically disclose a flexible circuit board assembly for transmission of energy to and from the antenna elements. However, Cudahy et al teach an electrode assembly mounted to a flexible pad (col. 5, lines 40-53) that is physically connected to a circuit (col. 7, lines 25-29). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to apply the teachings of Cudahy et al to Carr et al, Hirschman, and Culver et al, as to provide circuitry capable of being fit to a patient's geometry.

Regarding claims 4 and 22, neither Carr et al, Hirschman, nor Culver et al specifically disclose a flexible circuit board comprising at least one splitter such that electromagnetic energy can be transmitted to at least two of the plurality of antenna elements using a single transmission trace within the flexible circuit board. However, Cudahy et al teach the transmission of signals to a multitude of electrodes (col. 7, lines 25-29) through a single cable having a mating terminal connected to the plurality of electrodes (col. 6, lines 17-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to apply the teachings of Cudahy et al to Carr et al, Hirschman, and Culver et al, as to provide an electrical connection between a plurality of elements through a common cable.

Regarding claims 5 and 23, neither Carr et al, Hirschman, nor Culver et al specifically disclose a flexible circuit board comprises at least one combiner such that electromagnetic energy can be received from at least two of the plurality of antenna elements and carried by a single transmission trace within the flexible circuit board. However, Cudahy et al teach the

reception of electrical signals from electrode elements and the transfer of the signals through a single cable to a control system (col. 6, lines 17-33). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to apply the teachings of Cudahy et al to Carr et al, Hirschman, and Culver et al, as to provide an electrical connection between a plurality of elements through a common cable.

Response to Arguments

6. Applicant's arguments filed 10/1/10 have been fully considered but they are not persuasive. Following are responses to each of the applicant's unique argument in the order in which they are presented in the Remarks:

a. *Claims 27-33 are recited as being dependent upon claim 25, hence they are assumed to actually depend upon claim 26 in view of the preamble and claim limitations set forth, and therefore are also withdrawn from consideration. Claim 48 was previously listed as withdrawn from consideration but because it depends from claim 1, it has now been treated on its merits and therefore the current office action was not made Final.*

b. "However, the phrase 'the area of reduced sensitivity' was not mentioned in claims 12 and 19, therefore no changes were required.": *The corrections of claims 11 and 18 overcome the objection made. For future purposes, since claims 12 and 19 depend upon claims 11 and 18, claims 12 and 19 contain the limitations of their superior claims 11 and 18, and were thus objected as well.*

c. "Neither, Carr nor Hirschman, either alone or in combination teach or suggest Applicants' invention of Claims 1 and 13.": *Please see the rejections given in the present Office Action.*

d. "Further, Cudahy does not remedy any of the deficiencies of Carr and Hirschman": *The examiner disagrees. The teachings of Cudahy are appropriately combined with the disclosures of Carr and Hirschman since they are all directed to cutaneous measurements of subcutaneous biological events.*

e. "Thus there is no placement of the light sources and light detectors relative to the surface of the skin that will create areas of differentiate sensitivity therebetween. This is completely different that Applicants' invention and actually teaches away from the Applicants' invention because the sensors and light source can be any variety of distances from each other on the surface of the skin. In other words, the relative different of the light sensors and light source does not have any effect on sensing capability": *To the contrary, the teaching of Culver the applicant is referring to, namely, Fig. 7 and its associated description in column 7, lines 41-51, sufficiently applies in the combination set forth in the previous Office Action. Primarily, the limitation being covered in the claims with respect to this argument is that of an area of reduced sensitivity. This area of reduced sensitivity is made obvious by Culver's teaching that a differential sensitivity exists in between a source and a detector within the skin of the patient. This teaching is not in a direction away from the invention because they are both still directed to detecting extravasation.*

f. "However, Culver does not teach or suggest Applicants' invention of the location of the antenna pairs, namely, that 'the space between the first antenna element pair and the second antenna pair is set so that the sensor is insensitive to fluid changes of a predetermined volume within the area of reduced sensitivities.': *The examiner disagrees and directs attention to the rejection made on claims 11 and 18. Culver teaches that a prescribed threshold volume is determined for the purpose of controlling for excessive extravasation. This teaching sufficiently combines with the other arts for a proper obviousness rejection of this limitation since a predetermined volume within an area is set and detected.*

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Ip whose telephone number is (571) 270-5387. The examiner can normally be reached on M-F, 10am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached on (571) 272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JI/
Examiner, Art Unit 3777

/Ruth S. Smith/
Primary Examiner, Art Unit 3737